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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,200

06/27/2003

Jean-Marc Payrat

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06/16/2006

DIVII

EXAMINER

SAUCIER, SANDRA E

BAXTER HEALTHCARE CORPORATION

ONE BAXTER PARKWAY

DF2-2E

DEERFIELD, IL 60015

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/608,200

Applicant(s)

PAYRAT ET AL.

Examin r

Sandra Saucier

Art Unit

1651

-- The MAILING DATE f this communication appears on the cover sh et with the c rrespondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 37-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Pri rity under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 37–40 are pending and are considered on the merits.

Claim Rejections – 35 USC § 103

Claims 37–40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,250,303[CG].

The claims are directed to a composition comprising red cells suspended in a solution containing:

about 30–60 mM dextrose (45.4mM),
about 1.2–1.7 mM adenine (1.5mM),
about 30–50 mM mannitol (40mM),
about 4.5–55 mM sodium citrate (25mM),
about 2–5 mM sodium diphosphate (3.9mM),
about 8–18 mM sodium phosphate dibasic (16.1 mM),

substantially free of chloride and with an osmolarity of less than 300 mOsm.

Dependent claim concentrations are in parenthesis and include a pH of about 7.4.

US 5,250,303 discloses compositions comprising:

red cells suspended in a solution containing:

50–139mM dextrose (50mM),
0.01–2mM adenine (0.01M)
22–33mM sodium citrate (22mM),
mannitol (44mM),
2.5–2.9 mM sodium dihydrogen phosphate (2.5mM),
10.6–12mM sodium phosphate dibasic (10.6mM),
pH 7.4–7.5, osmolality around 200mOs.

as exemplified in Table 2, ARC8, ARC 27, ARC30.

Although the specifically exemplified ARC30 has only 0.01mM adenine, adenine is shown to be present in similar solutions in concentrations up to 2mM. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. This is considered to be routine experimentation well within the purview of one of skill in the art in the absence of evidence to the contrary. See MPEP 2144.05 I. and II.

One of ordinary skill in the art would have been motivated at the time of invention to make these changes in concentrations in order to obtain the resulting composition as suggested by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 4/24/06 have been fully considered but they are not persuasive.

Applicant argues that the solutions of US 5,250,303 are five distinct solutions and that the reference demonstrates that the concentration of adenine in red cell solutions is not critical. The examiner agrees with this position, therefore, in the absence of criticality, one of ordinary skill in the art may use any concentration of adenine from 0.01mM to 2mM in a red cell solution as demonstrated in US'303. Evidence to the contrary will be carefully considered. All components of the composition now claimed have been used together in concentrations which overlap the instant concentrations in the prior art for the same purpose, that is, as a red cell suspension medium.

Please note that Example 13, the adenine concentration of ARC8 which does not include mannitol has been reduced. This demonstrates that the inclusion of mannitol is not tied to the lowering of the adenine concentration. And is, in fact independent of whether or not mannitol is in the solution.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case, all components of the composition now claimed have been used in red cell solutions in concentrations which are within the instant ranges in the prior art for the same purpose, that is, as a red cell suspension medium.

A showing that the concentration of adenine is critical, contrary to the teaching of US'303, would advance prosecution.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due

to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
June 9, 2006